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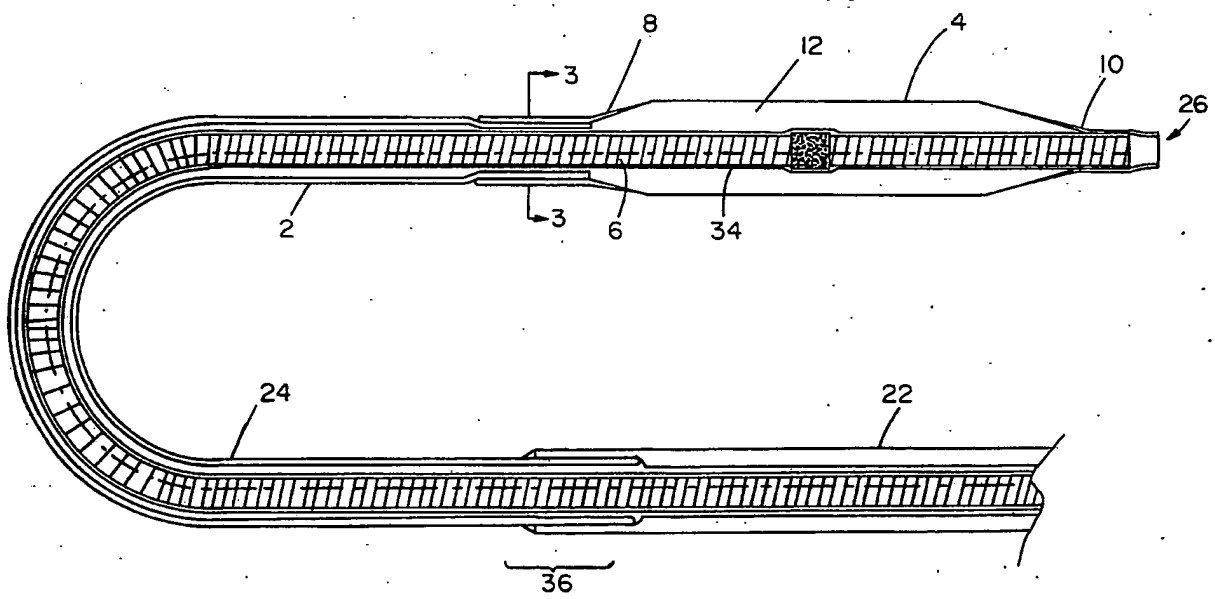


(57) Abstract

An over-the-wire dilatation catheter with a spring coil inner lumen is disclosed. The wound wire of the spring coil inner lumen is preferably stainless steel flat wire, and the preferred dimensions for the flat wire are 0.0015 inch by 0.006 inch. Usually the inner lumen is jacketed with a biocompatible polymer, preferably polyethylene, and it may be enhanced by a lubricious coating on the interior. The outer shaft is preferably comprised of a stiffer proximal and a more flexible, narrower distal portion.

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# CATHETER WITH SPRING COIL INNER LUMEN

## BACKGROUND OF THE INVENTION

Field of the Invention:

This invention relates to catheters for coronary angioplasty, particularly over-the-wire dilatation catheters.

Description of the Prior Art:

Catheters are tube-like members that are inserted into the body for various medical reasons, some diagnostic and others therapeutic. In general, catheters used for coronary angioplasty have an outer tube or shaft with a balloon near the distal tip. The catheter is threaded into the vasculature, with the balloon located within the stenosis. The balloon is then inflated to redistribute the plaque of the stenosis along the artery wall so that it does not block the artery.

In some catheters, an attached stiffening wire extends through the shaft to the tip to aid in the insertion of the catheter into the arteries, which are twisted and tortuous. In some catheters, a separate inner tube, or lumen, extends within the outer tube to hold the guidewire. Where the catheter is a fixed-wire catheter, the guidewire is fixed in place within the inner tube; when the catheter is an over-the-wire catheter, the guidewire is a separate unit which extends through the inner tube and out the open far end.

Among the considerations in designing the catheter is the axial strength of the system. The catheter must be sufficiently strong so that pushing the catheter at the user's end results in forward motion at the distal end. Where the catheter has an inner tube or lumen, it must be strong enough to avoid collapse when the catheter extends around a corner.

Some catheters use metal in some locations in the catheter. In Kraus, et al., EPO publish d application 397,055, published November 14, 1990, the proximal end of th catheter shaft is formed of stainless steel, and a stainless steel coil forms the distal tip of the catheter beyond the balloon. A tip coil is also provided in Mar, U.S. Patent No. 4,771,778, issued September 20, 1988. In Schulte, U.S. Patent No. 3,738,365 issued on June 12, 1973, a small part of what is essentially the outer lumen of a drainage catheter is made extensible by including a metal coil.

In Sheldon, U.S. Patent No. 3,060,972, a flexible tube structure for an endoscopic device is formed of a plurality of end-to-end tubular units. In Bundy, et al., U.S. Patent No. 4,653,496, a helically wound coil having a concentric outer radial cutting cannula is disclosed for the removal of stenotic and occlusive lesions from the vascular system. In Goldberg, et al., U.S. Patent No. 4,351,341, issued September 28, 1982, Samson, et al., EPO publication 356,748 and Bazell, et al., U.S. Patent No. 4,444,188, issued April 24, 1984, the outer lumen of a balloon catheter includes a coil; the same is the case in Sharrock, U.S. Patent No. 4,368,730, issued January 18, 1983, which discloses a catheter-like introducer.

In Machold, et al., EPO publication 297,959 published August 31, 1988, the proximal end of the inner tube of a dilatation catheter has a stainless steel liner. In Pinchuk, et al., U.S. Patent No. 4,946,466, a balloon is affixed to a metallic, hollow guidewire.

In Dick, EPO published application 388, 486, published September 26, 1990, a dilatation catheter has a regulating expanding device embodied in a connector having an "interlumen" made of a tightly wound polymer-coated metal coil.

In Buchbinder, et al., U.S. Patent No. 4,723,936, issued February 9, 1988, and owned by the assignee of the present invention, a catheter, fixed-wire, is disclosed which has an inner tube formed of coiled stainless steel flat wire.

In Hess, U.S Patent No. 4,808,164, issued February 28, 1989, and No. 4,927,413, issued May 22, 1990, a generally fixed-wire catheter is disclosed. The inner lumen is formed of a suitable metal and has an outside diameter of about 0.014 to 0.035 inches. A core is movably and removably mounted inside the lumen. A small "guidewire" extends from the distal tip of the catheter in some embodiments. In others, it extends from the distal tip of the core. Because the Hess catheters are essentially fixed-wire systems, with a core designed particularly to fit the inner lumen, they are not available for use and insertion over a standard guidewire.

This can be a disadvantage of the Hess device. The core designed to go with the catheter must be used in most cases, and the catheter cannot be used in a system in which a small guidewire needs to be carefully steered through a tortuous pathway ahead of the lesion, and the catheter then moved over the guidewire into place. What is apparently coils of round wire shown in the Hess device and a standard guidewire may easily lockup around corners if used together because the standard wire also has a round coil. Finally, because the device appears to use a round coil, it lacks the axial strength and "pushability" which is needed in an over-the-wire catheter which does not have the added stiffening of a fixed wire.

The above description of art is not intended to constitute an admission that any patent, publication or other information referred to is "prior art" or is enabling with respect to this invention, unless specifically designated as such. In

addition, this section should not be construed to mean that a search has been made or that no other pertinent information as defined in 37 C.F.R. § 1.56(a) xists.

## SUMMARY OF THE INVENTION

The invention in one aspect is an over-the-wire catheter with a spring coil inner lumen which avoids problems associated with the prior art. It includes an outer shaft, a balloon attached to the outer shaft and adapted for inflation through the outer shaft, and a cylindrical inner tube comprised of a wound wire extending within the inner shaft, the inner tube being open at the distal end to form a lumen for a separate guidewire.

The wound wire is preferably made of stainless steel flat wire, and the preferred dimensions for the flat wire are 0.0015 inches by 0.006 inches. Usually the inner lumen is jacketed with a biocompatible polymer, preferably polyethylene. Sometimes a lubricious coating is applied to the interior of the inner lumen, and the outer shaft may be made of more than one material to enhance both stiffness and flexibility, while maintaining a good-sized inflation lumen.

## BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a plan view of the entire catheter.

Fig. 2 illustrates a transition zone between the proximal and the distal portion of the outer shaft of the catheter.

Fig. 3 is a cross-section of the catheter taken at lines 3-3 of Fig 2.

## DESCRIPTION OF THE PREFERRED EMBODIMENTS

The catheter 1 of the present invention is shown generally in Fig. 1. It includes a tubular outer shaft 2, a generally cylindrical inflatable balloon 4, and an inner tube or lumen 6. The balloon is heat shrunk at its proximal end 8 to the outer shaft, and at its distal end 10 to the inner tube, about 2 mm back from the distal tip 26 of the catheter. The balloon preferably has a 20 cm working length.

The outer shaft and inner tube define a lumen 30 therebetween shown on Fig. 3, a cross-section of the catheter. This lumen is used for inflation of the balloon and is open to the interior 12 of the balloon. A Y-shaped manifold 14 of polycarbonate is attached to the outer shaft at the proximal end, via a transition zone of strain relief tubing 26 and 28 formed of polyethylene (preferably Rexene 1017). It includes one arm 16 accessing the inflation lumen for inflation of the balloon.

The manifold has a second arm 18 which accesses the guidewire lumen 20. Guidewire lumen 20 extends the length of the catheter within the inner tube 6. It is designed so that a guidewire (32 shown in dotted lines in Fig. 3) can be slidingly inserted therethrough. The distal end 26 of the inner tube 6 is open so that the guidewire can be extended through and out the distal end of the catheter.

The inner tube, i.e., the "spring inner lumen" is comprised of a helically wound coil of a biocompatible material. The wire from which the coil is wound is preferably a flat wire, which gives the inner tube advantageous characteristics. In particular, it provides a smoother surface so that a guidewire (particularly a standard one with round wire) can be easily slid through. Because of the relatively large mutually-contacting surface of adjacent coils of flat wire, axial strength and stiffness is greater than in the case of

round wire even while a thinner wire is used to minimize the catheter profile.

In the preferred embodiment, the flat wire is formed of stainless steel (metal is preferred because it does not deform as do most polymers used for tubing) with dimensions of about 0.0015 by 0.006 inches. These dimensions appear to maximize axial strength and flexibility while maintaining desired catheter dimensions. However, other sizes can be used such as those ranging from about 0.001 to 0.003 inches in thickness and about 0.004 to 0.001 inches in width.

The inner lumen has a heat shrunk jacket 34 formed of a low density polyethylene, such as Rexene 1017. A marker band is located at the center of the balloon, is formed of gold, and is heat shrunk into place by the polyethylene jacket. A lubricious material such as Enhance™ silicone coating may be coated on the inner surface to enhance handling of the guidewire. The entire spring coil, before it is wound or jacketed, may be coated with other materials such as Teflon™ to enhance lubricity or provide other advantages. In some embodiments, the spring coil has been plated with gold.

When intended for use with a guidewire up to about 14K (0.014 inches) in size, the inner diameter of the inner tube is about 0.017 to 0.019 inches, and the outer diameter of the coil itself is about 0.022 inches. The overall diameter of the inner tube with jacket is about 0.024 to about 0.025 inches.

The outer shaft 2 is preferably formed of a biocompatible flexible material such as those known in the art for use in catheters. Particular materials can be polyimides, polyethylenes, and the like. In the preferred embodiment, two materials are used. The proximal portion 22 of the shaft, usually about 105 cm long, is formed of polyethylene

terepthalate, preferably Traytuf PET #7200c, and the distal 28 cm or so of the shaft, 24, is f rmed of polyethylene, preferably Rexene 1017.

The joint 36 between the two portions of the shaft, which is about 5 mm long in the preferred embodiment, is illustrated on Fig. 2; the two portions are overlapped and joined by a biocompatible adhesive such as cyanocrylate. The dual materials are included because PET forms a stiffer shaft than the polyethylene; it provides a stiff proximal end where the catheter is pushed by the user. The polyethylene distal shaft provides more flexibility for a more easily-steerable tip; in addition, the profile of the polyethylene portion is kept smaller for ease of tracking in the coronary vessels. The inner diameter of the PET outer shaft is preferably about 0.034 inches, while the outer diameter is preferably about 0.042 inches. The polyethylene portion, in contrast, has an inner diameter of about 0.031 inches and an outer diameter of about 0.038 inches.

It will be understood that the above description and the illustrations are provided by way of example only, that alternate versions, equivalents, and examples will be apparent to those skilled in the art, and will be within the scope of the invention which is defined by the appended claims.

WHAT IS CLAIMED IS:

1. A cath ter comprising:

an outer tubular shaft;

a balloon attached to the outer shaft and adapted for inflation through the outer shaft;

a cylindrical inner tube comprised of a wound wire extending within the inner shaft, the inner tube being open at the distal end to form a lumen for a separate guidewire.

2. A catheter according to claim 1 and wherein the wound wire is made of metal.

3. A catheter according to claim 2 and wherein the wound wire is flat wire.

4. A catheter according to 3 and wherein the flat wire is stainless steel having dimensions of about 0.0015 inches by 0.006 inches.

5. A catheter according to claim 1 and wherein the wound wire is jacketed with a biocompatible polymer material.

6. A catheter according to claim 5 and wherein the jacket is formed of polyethylene.

7. A catheter according to claim 2 and wherein a lubricious coating is applied to the interior of the inner tube.

8. A catheter according to claim 1 and wherein the outer shaft is formed of polyethylene terepthalate at its proximal portion and polyethylene at its distal end.

9. A catheter according to claim 1 and wherein about the proximal three-quarters of outer shaft has a greater outer diameter than the distal portion.

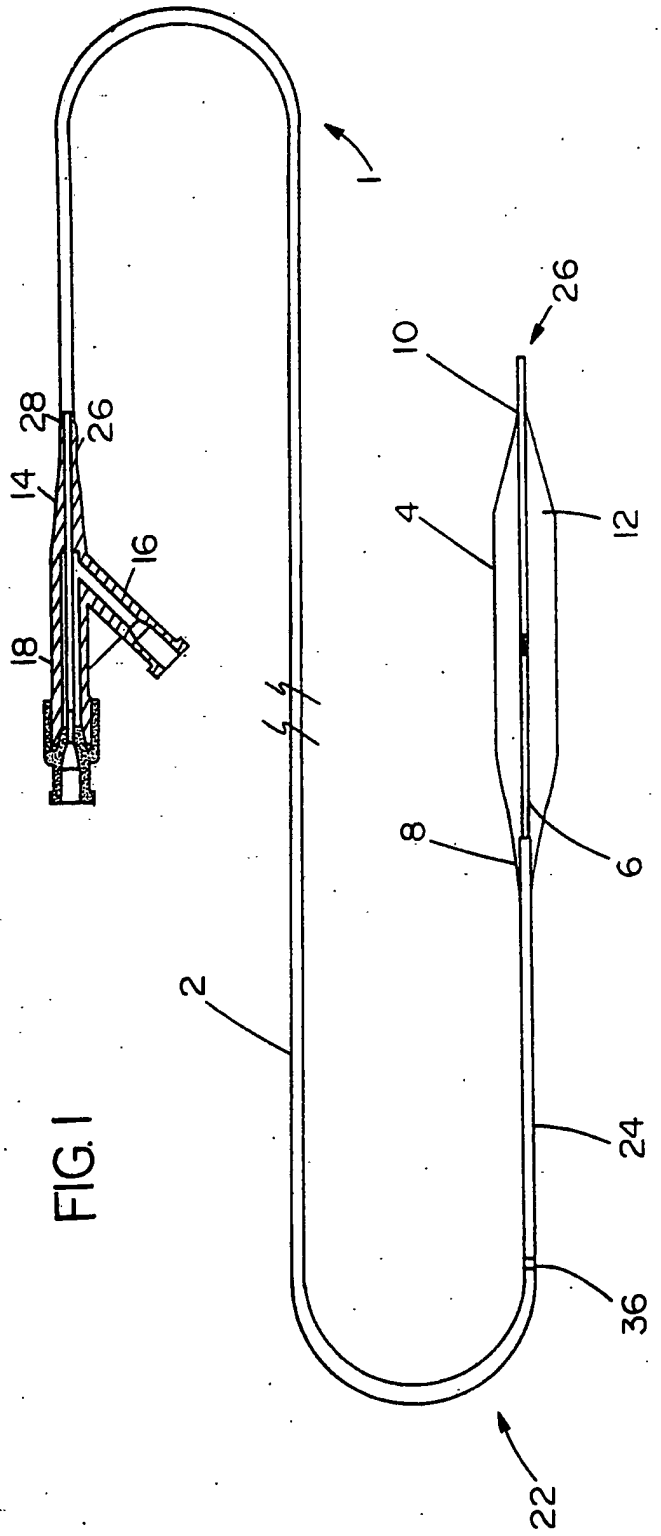


FIG. 1

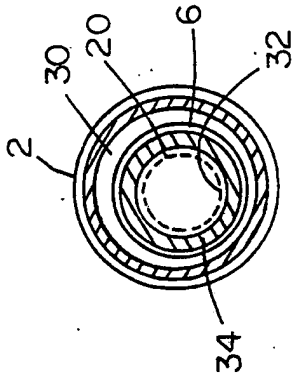


FIG. 3

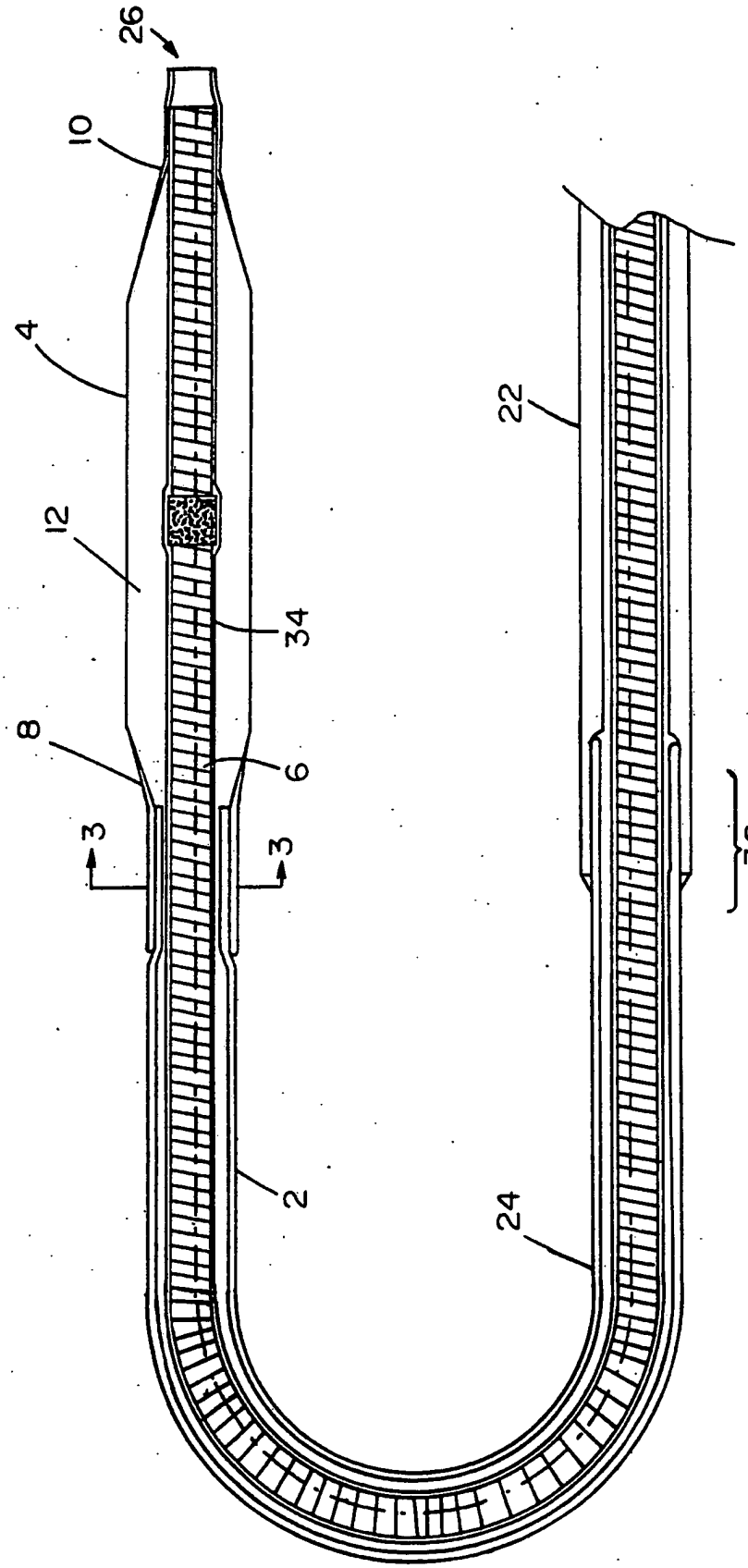


FIG. 2

# INTERNATIONAL SEARCH REPORT

PCT/US 92/07948

International Application No

## I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61M29/02

## II. FIELDS SEARCHED

Minimum Documentation Searched[7]

| Classification System | Classification Symbols |
|---|---|
| Int.Cl. 5 | A61M |

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

## III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

| Category ° | Citation of Document, [11] with indication, where appropriate, of the relevant passages [12] | Relevant to Claim No.[13] |
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| A | EP,A,0 397 459 (MEDTRONIC)<br>14 November 1990<br>see column 4, line 7 - line 33; figures<br>1,5,6,8 | 1-4 |
| A | WO,A,8 200 592 (URESIL)<br>4 March 1982<br>cited in the application<br>see abstract; figures 1-5 | 1,2,4 |

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## IV. CERTIFICATION

| Date of the Actual Completion of the International Search | Date of Mailing of this International Search Report |
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| 22 JANUARY 1993 | 01.02.93 |
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III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

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# ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

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This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on
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